



RECEIVED

MAR 19 2002

TC 1700

REMARKS/ARGUMENTS

The Office Action mailed January 29, 2002 has been carefully reviewed.

Reconsideration of this application, as amended and in view of the enclosed Declarations and the following remarks, is respectfully requested.

35 USC §112 Rejections

In the Office Action mailed January 29, 2002 the Examiner rejected claims 2, 3, 5, 6, 12, 13, and 15 under 35 USC §112 alleging that the phrase "such as" renders claims 2, 3, 5, 12, 13, and 15 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention and that there is insufficient antecedent basis for the limitation "said circulation system" in claim 6.

Applicant has amended claims 2, 3, 5, 12, 13, and 15 to eliminate the phrase "such as" and to make it clear the limitations following the phrase are part of the claimed invention. Applicant has amended claim 6 to provide an antecedent basis for the limitation "said circulation system." The individual amended claims are set out in "clean" form above. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made." Applicant submits that the rejection of the claims under 35 USC §112 have been fully addressed and overcome.

### 35 USC § 102 Rejections

In the Office Action mailed January 29, 2002 the Examiner rejected claims 1 and 7 under 35 U.S.C. 102(e) as being anticipated by Berry (U.S. Pat. 6,293,861).

Enclosed are two declarations: "Declaration of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent" and a "Declaration by Eddie E. Scott of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent." Applicant submits that the two declarations establish that Applicant made the invention described and claimed in the subject patent application in this country prior to September 3, 1999 which is the filing date of the application from which Berry (U.S. Pat. 6,293,861) matured. Applicant submits that the Berry reference, U.S. Pat. 6,293,861, can not be used as a reference against the claims of the subject application.

### 35 USC § 103 Rejections

In the Office Action mailed January 29, 2002 the Examiner made the following rejections under 35 USC § 103:

Claims 6 and 8-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mascolo et al. (U.S. Pat. 5,078,046) in view of Berry;

Claims 2, 3 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Berry in view of Groger et al. (U.S. Pat. 5,766,956);

Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Berry and in view of Anbar (U.S. Pat. 4,022,876);

Claims 12, 13, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mascolo et al. in view of Berry as applied to claim 11 and further in view of Groger et al.;

Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Mascolo et al. in view of Berry as applied to claim 11 above and further in view of Anbar; and

Claims 16-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mascolo et al. in view of Berry as applied to claim 11 and further in view of Condit et al. (U.S. Pat. 5,938,823).

Enclosed are two declarations: "Declaration of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent" and a "Declaration by Eddie E. Scott of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent." Applicant submits that the two declarations establish that Applicant made the invention described and claimed in the subject patent application in this country prior to September 3, 1999 which is the filing date of the application from which Berry (U.S. Pat. 6,293,861) matured. Applicant submits that the Berry reference, U.S. Pat. 6,293,861, can not be used as a reference against the claims of the subject application. Since the Berry reference can not be used, Applicant submits all of the above rejections under 35 USC § 103 have been overcome.

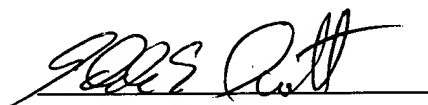
The two declarations, "Declaration of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent" and a "Declaration by Eddie E. Scott of Prior Invention by Raymond P. Mariella, Jr. to Overcome Cited Patent," include a number of Attachments. These Attachments include reports and documents provided for under Contract No. W-7405-ENG-48 between the United States Department of Energy and the University of California for the operation of Lawrence Livermore National Laboratory and reports required by the sponsor of the research conducted by Applicant. These reports and documents are internal unpublished government reports. They maintained in strict privacy and secrecy and are considered Business Sensitive. In obtaining copies of these reports and documents, Applicant became aware of various presentations. Enclosed with this Amendment is a supplemental "Information Disclosure Statement" providing information about the various presentations.

#### SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments, the enclosed Declarations, and the foregoing remarks, the rejections of the claims raised in the Office Action dated January 29, 2002 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the

present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Eddie E. Scott", written over a horizontal line.

Eddie E. Scott  
Assistant Laboratory Counsel  
University of California  
Lawrence Livermore National Laboratory  
Attorney for Applicant  
Registration No. 25,220  
Tel. No. (925) 424-6897

Dated: February 27, 2002  
Livermore, California



Application No.: 09/662,392

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Page 10, line 2, change the word "and" to -- an -- ; (paragraph starts on page 9, line 1 and ends on page 10, line 3)

There is an increasing need for a system for detecting and treating biological and chemical warfare agents. The threat of an attack with chemical or biological weapons on U.S. citizens is a high priority concern. Events such as the World Trade Center and Oklahoma City bombings, the Tokyo subway nerve gas attack, the Sverdlovsk Soviet Union release of dry anthrax spores, and several bio-terrorism scares have accelerated private and U.S. Government efforts to combat terrorism, particularly chemical and biological terrorism. In the face of the potential for chemical and biological terrorism, the country's national security is increasingly defined by its ability to respond with new technology. Biological warfare is the intentional use of micro-organisms and toxins, generally, of microbial, plant, or animal origin to produce disease and/or death in humans. This can be accomplished directly, through the food supply, through the water supply, or through the air supply. Biological agents are of particular concern because of the ease with which they can be manufactured, transported, and dispensed. Because of the lag time between a biological attack and the appearance of symptoms in those exposed, biological weapons could be

devastating. Many biological agents are contagious; and during this lag time, infected persons could continue to spread the disease, further increasing its reach. Hundreds or even thousands of people could become sick or die if a biological attack were to occur in a major metropolitan area. Because the lethality of an airborne pathogen depends upon its concentration, the greatest threat to our citizens would be the release of a quantity of agent into [and] an enclosed airspace of an occupied building.

---

Page 11, line 8, after the word "detector" add a comma (,) ; (paragraph begins in page 11, line 6 and ends on page 11, line 13).

---

The vast majority of buildings need not resort to such an expensive, maintenance-intensive approach, since most buildings will never be the target of a BW agent attack. Following the basic concept of a smoke detector, the present invention minimizes the maintenance burden to a building. That is, the HVAC system would operate essentially unchanged once the new system is installed, except that the new system could activate a precipitator/scrubber if a pathogen were detected in the air supply. Absent this detection, the annual maintenance burden would be only slightly increased.

---

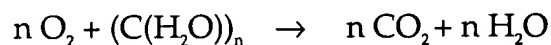
Page 13, line 16, change "one to five" to -- one-to-five -- ; (paragraph begins on page 13, line 10 and ends on page 13, line 19).

The risk posed by chemical agents has two components: a vapor and liquid hazard. Airborne chemical agents can be contacted by humans through inhalation or dermis absorption. An array of chemical point detectors and alarms that can provide real time warnings of exposure are available. In contrast, the hazard posed by airborne biological agents is primarily an inhalation one. The most effective means of delivering a biological agent is via an aerosol in the [one to five] one-to-five  $\mu$ m particle size. Creation of this type of an invisible aerosol cloud could be efficiently accomplished using a sprayer, as was demonstrated by the US Official BW program that was unilaterally terminated in the 1960s.

---

Page 14, line 10, change "ect." to – etc. -- ; (paragraph begins on page 13, line 20 and ends on page 14, line 10).

Chemical and toxin attacks can have immediate effect. Pathogen detectors for human respiration need to focus on the following considerations. A calculated respiratory exchange rate, assuming 15% aerobic efficiency, when burning approximately 100 calories/hour with



is 10 liters of air/minute. Starting with 1 ACPLA of B.a., where one particle can be assumed to consist of 15 spores, then a person, assuming high efficiency for deposition and germination of spores in the lungs, would receive a lethal dose of 8000 to 10,000 spores in roughly 1 hour. The respiratory exchange rate can be



considered to be higher, 15 liters of air/minute, when you include the sinus cavity, throat, trachea, larynx, mouth, [ect.] etc.

Page 17, line 5, change “detects” to – employs -- ; (paragraph begins on page 16, line 15 and ends on page 17, line 6).

The APDS, identified generally by the reference numeral 22, includes aerosol collector 23, a system for capture of antibody coated beads 24, a biotin labeled antibody system 25, a fluorescent labeled streptavidin system 26, a flow controller 35, a detector 34, a laser 33, and a flow cytometer<sup>32</sup>. The objective is to combine the ultrahigh sensitivity and selectivity of PCR-based biodetection of biological agents with the more general assays that can be performed with flow cytometry. Flow cytometry (FCM) is a technique used to characterize and categorize biological cells and/or their contents, such as DNA, to record their distributions, and can also be used to sort biological material. The biological cells are present in an aqueous-based solution, even when the sample material is eluted from a matrix, such as in sheath-flow detection in electrophoresis experiments APDS may operate using a hybrid instrument that [detects] employs both antibody based assays and PCR assays.

Page 19, line 22, after the word "light" insert – (RAS includes both PLS and inelastically-scattered light) -- ; (paragraph begins on page 19, line 15 and ends on page 20, line 7).

The flow cell cytometer 32 can also be a system such as that disclosed and claimed in U. S. Patent Application No. 09/027764, filed February 23, 1998, by Raymond P. Mariella, Jr. for Waveguide Detection of Right-Angle-Scattered Light In Flow Cytometry, which is incorporated herein by reference. That system uses a transparent flow cell as an index-guided optical waveguide, similar in some respects to U.S. Patent No. 5,475,487. A detector for the flow cell but not the liquid stream would then be used to detect the Right-Angle-Scattered (RAS) Light (RAS includes both PLS and inelastically-scattered light) exiting from one end of the flow cell. As before, the detector(s) could view the trapped RAS light from the flow cell either directly or through intermediate optical light guides. If the light exits the end of the flow cell referred to as "bottom," then the top of the flow cell could be given a high-reflectivity coating to approximately double the amount of light collected. This system would be much more robust in its alignment than the traditional flow cytometry systems which use imaging optics, such as microscope objectives.

Page 25, line 5, change "grams" to – gram -- ; (paragraph begins on page 25, line 4 and ends on page 25, line 10).

Biological agents are many times deadlier, pound-for pound, than chemical agents. One [grams] gram of anthrax spores could kill as many people as a ton of the nerve agent sarin. There are four distinct types of chemical weapons: nerve, blister, blood, and incapacitating agents. The effects from these chemical agents can occur within seconds of exposure as in the case of nerve and blood agents or as long as several hours in the circumstance of low-dose blister agent exposure such as mustard gas.

#### **IN THE CLAIMS**

2. (Amended) The system for the detection and treatment of unwanted agents of claim 1 wherein said detection system utilizes immunoassays[, such as] and said immunoassays include antibody based or synthetic-peptide based immunoassays.

3. (Amended) The system for the detection and treatment of unwanted agents of claim 1 wherein said detection system utilizes nucleic-acid-based assays[, such as the] and said nucleic-acid-based assays include polymerase chain reaction immunoassays.

5. (Amended) The system for the detection and treatment of unwanted agents of claim 1 wherein said detection system utilizes a plurality of assays[, such as] and said detection system utilizes a plurality of assays include antibody

based or synthetic-peptide based immunoassays, nucleic-acid-based assays[, such as the] and said antibody based or synthetic-peptide based immunoassays, nucleic-acid-based assays include polymerase chain reaction immunoassays, and mass-spectrometric-based assays.

6. (Amended) The system for the detection and treatment of unwanted agents of claim 1 including a circulation system for circulating said air to said detection system and said treatment system and a control connected to said treatment system and said circulation system for inactivating said circulation system if said treatment system shuts down prematurely.

12. (Amended) The apparatus of claim 11 wherein said autonomous chemical and pathogen detector utilizes immunoassays[, such as] and said immunoassays include antibody based or synthetic-peptide based immunoassays.

13. (Amended) The apparatus of claim 11 wherein said autonomous chemical and pathogen detector utilizes nucleic-acid-based assays[, such as] and said nucleic-acid-based assays include the polymerase chain reaction.

15. (Amended) The apparatus of claim 11 wherein said autonomous chemical and pathogen detector utilizes a plurality of assays[, such as] and said

plurality of assays include antibody based or synthetic-peptide based immunoassays, nucleic-acid-based assays[, such as] and said antibody based or synthetic-peptide based immunoassays, nucleic-acid-based assays include the polymerase chain reaction immunoassays, and mass-spectrometric-based assays.